Department of Mental Health and Addiction Services
Institutional Review Board - Office of the Commissioner
Quality Management and Improvement
410 Capitol Avenue MS # 14
PO Box 341431
Hartford, CT 06134

REPORT OF PROTOCOL DEVIATION

Please complete form, print out and submit signed copy. Report may be forwarded to the IRB chair electronically but must be followed by signed hard copy.

Date of report:

Title of study:

DMHAS Study ID Number:

Principal investigator
Name and Title:
Phone:
Fax :
E-mail:

Date of protocol deviation: **Date investigator became aware of deviation:**

Study site involved:

Number of study participants involved or affected by deviation:

Description of protocol requirement:

Description of protocol deviation:

Please describe action taken to ameliorate any discomfort or negative consequence related to the protocol deviation:

Please describe action taken to reduce/eliminate likelihood of recurrence:

Is a revision of procedures planned in response to the protocol deviation? ☐ **yes** ☐ **no**

Description of any action planned or taken as a result of deviation such as internal procedural change; intervention with research staff; consent form change; protocol change; etc.:

_____ _____

Principal Investigator – Signature **Date**